III. **Remarks**

Claim Rejections – 35 USC §112

Claims 1, 4-14 and 24-25 stand rejected under 35 USC §112 first paragraph as failing to comply with the written description requirement in that claim 25 recital of "optically active acids" is without foundation in the specification and the term R' is not defined in the specification so as to determine the structures included in R'.

Applicant respectfully traverses this rejection.

As to the reference to "optically active acids" applicant refers the examiner to page 12, lines 12 – 18 of the specification where optically active acids are specifically mentioned.

As to R', the scope of R' is broadly defined at page 5, lines 14 et seq. as being any compound inert under the conditions of a Grignard reagent. Any person skilled in the are of these types of chemical reactions is knowledgeable as to which compounds will react under the conditions of a Grignard regent. This definition is elucidated by the language immediately following which provides that such compounds include a $(C_1\text{-}C_6)$alkyl, $(C_1\text{-}C_3)$alcoxy$(C_2\text{-}C_4)$alkyl. Advantageously employed compounds are , a benzyl, a diphenylmethyl or triphenylmethyl group, unsubstituted or substituted on the benzene rings with one or more groups independently chosen among $(C_1\text{-}C_6)$alkyl, $(C_1\text{-}C_3)$alcoxy and nitro groups or with a 2, 3- or a 3, 4-methylenedioxy group. Preferably, R' is an optionally substituted triphenylmethyl or diphenylmethyl group$(C_1\text{-}C_6)$alkyl, $(C_1\text{-}C_3)$alcoxy.

Claim Rejections - 35 USC 103(a)

Claims 1-14 and 24-25 stand rejected under 35 USC 103(a) as being unpatentable over Guazzi et al WO 02/48133.

The examiner states that the fact that the substituted hydroxylamine compounds are applicable in the process implies they are analogous compounds of hydrozylamine.

Applicant respectfully traverses this rejection.

Applicant claims a process for making Citalopram from 5-formylphthalide as set forth in steps (a) to (f) of claim 1.

Initially, applicant notes that his claims are process claims and that the similarity or dissimilarity of the process steps should be the primary focus.

Guazzi et al. and applicant start with 5-formylphthalide and manufacture Citalopram. However the process steps utilized are substantially different. This is readily seen when Guazzi et al's reaction scheme, appearing at page 4 of their specification is compared with applicant's reaction scheme appearing at pages 3 and 4 of the present specification. Guazzi et al. states, at page 3, lines 3-6 that the essence of his invention is a process "starting from a 5-formylphthalide acetal (VII), according to the following scheme ...".

Applicants do not utilize the 5-formylphthalide acetal of Guazzi et al. in their process.

Guazzi et al states at page 6, lines 5 et seq. that the benzofuran ring closure step in his process allows the conversion in a single step of the compound of formula (III) into Citalopram. This step is missing from applicants process where R' is removed in a first step and the oxime is converted into a nitrile in a second step.

The examiner then states that Guazzi et al. teaches a similar process of making Citalopram, citing the reaction scheme at page 4 of applicants specification. The examiner notes that there is a difference between Guazzi et al. and the present invention in that Guazzi et al.'s second last step in the process is the first step in applicant's process and that applicant does not perform the first step of Guazzi et al., the conversion of 5-formylphthalide to the corresponding acetal.

Applicant respectfully would point out that the examiner is focusing on only one portion of applicants claimed scheme and on only one portion of Guazzi et al.'s scheme. However, applicant is claiming a complete reaction scheme, including steps (a) to (f) of claim 1. a comparison of applicant's entire process with Guazzi et al.'s entire process discloses multiple

differences in moving from the 5-formylphthalide starting material and ending in the Citalopram product.

Thus, Guazzi et al. modifies his starting material (VIII) in a series of process steps to form compounds of formulas (VII), (VI), (V), none of which are formed in applicant's process. On the other hand, applicant reacts the starting material to form an oxime of formula (III) which is not formed in Guazzi et al.'s process.

Thus, multiple process steps are different.

The examiner states that all the reagents in the instant inventions steps are the same as those of Guazzi et al. This is not correct, as demonstrated above, in that the reagents in the intermediate steps are clearly different.

The examiner concludes that the instant process is a selective combination of Guazzi et al. But while stating that the instant process is a "selective combination" the examiner does not specify what two or more things or processes are being selectively combined to demonstrate the steps of applicant's process. Thus, *In re Mostovych*, cited by the examiner, is inapposite.

Finally, the examiner and that the use of an analogous starting material in a well-known process is prima facie obvious.

Applicant respectfully disagrees. Here we do not have a situation where the starting [5-formylphthalide] and ending [Citalopram] materials are different and where the process is the

same. Here we have the same materials but the processes are different. *In re Durden,* cited by the examiner, is therefore inapposite.

Respectfully submitted,

Serle Ian Mosoff
Reg. No.25,900

CUSTOMER NUMBER 026304
KATTEN MUCHIN ZAVIS ROSENMAN
575 Madison Avenue
New York, NY 10022-2585
(212) 940-8717
Docket No.:
SIM: pm